Dietary Supplement Research Group

FINAL REPORT

A Randomized, 3-Arm Comparative-Controlled, Double-Blinded, Cross-Over-Group, Clinical Trial to Test the Short-Term Efficacy and Safety of Company ABC's Energy Drink™ In a Comparison with Other Energy Drinks

May 11, 2007

PROTOCOL CONCEPTS

- Prospective, randomized, double blind, comparative-product clinical trial
- This trial had IRB approval;
- Randomization determined on any given test day, which product an individual would take (placebo or one of the three products);
- There was a minimum of a 48-hour washout period. It was important to allow each subject time to completely recover from their test day;
- All subject contact was with a study coordinator or research nurse who was blinded to the randomization scheme
- This was a single-center, prospective, randomized, double-blinded, and product-controlled, crossover-group-design clinical trial of Company ABC's Energy Drink™ versus two other energy blends in subjects who are wishing to assess these products for increased short-term energy.
- Subjects were recruited from the greater Portland, Maine area, through CATV advertising.
- At the outset, subjects will be instructed that these blends are intended to induce energy increases without the need to make major behavioral changes. If they wish to participate, subjects must do their best to keep their diet patterns as consistent as possible throughout the study period (approximately four weeks). With respect to food, we will strongly urge subjects to be consistent with the TYPE and AMOUNTS of food consumed during the study period. We want subjects to keep their normal patterns of diet and wish to avoid subjects changing their fundamental diets during the four weeks of the study. We will explain that the product has the possibility of altering their appetite levels during the testing day. We plan to use food logs and to train our nurses to gauge the quantity of food intake and type of food consumed.

Initial Visit

- Consenting Process:
    - Following a successful screening phone call, in which the research staff briefly explained the study and subject responsibilities, queried the potential subject about availability, some medical conditions that might exclude them, and answered any questions.

  - An appointment was set for an initial meeting;
  - At their Initial Visit, potential subjects were given a copy of the informed consent (IC) to review. Subsequently, research staff (PI or study coordinators) thoroughly reviewed the consent form with each prospective subject according to appropriate guidelines. Each paragraph in the IC was reviewed and subjects were allowed adequate time to make an informed decision. Subjects were allowed to take the IC home to review with family members or their medical provider.
  - If agreed, both reader and subject will sign according to guidelines; subjects signed the back sheet and initialed each page;
  - No procedures were done unless signed consent has been obtained.
- After consenting, subjects had their weight, height, blood pressure, pulse, and blood glucose measured.
- If a subject medically qualified for the study with respect to glucose control (non-fasting blood glucose less than 140 mg/dL, fasting less than 126), subjects were allowed to continue in the study;
- For those that failed their glucose numbers, permission from our study physician or their own physician were obtained; NOTE: we did not have any subjects in this study that failed their initial glucose levels;
- All subjects at this point will be randomized for the metabolic testing. Those randomized to receive the metabolic testing will have this testing conducted during the run-in test days. Actual product randomization will not occur until the first test-day.
- All subjects will have blood drawn for a comprehensive metabolic profile for the purposes of screening. These results were reviewed prior to their day 1 testing. Some abnormal labs would have resulted in disqualification, such as extremely elevated serum creatinine, BUN, liver enzymes, and related levels. Thankfully, no disqualifications occurred in this population, although some subjects had slightly elevated laboratory values. Each set was reviewed and elevated values were reviewed with our medical director. There was no follow-up lab work scheduled in this study because these energy drinks provide no reason to alter chemistries.
- Females of child-bearing potential provided a urine sample for pregnancy testing. Positive pregnancy testing would have been cause for disqualification although none were and all females were allowed to continue.

Test-Day Routines

- There were two test days during the baseline run-in period for the purpose of establishing normal existing patterns of diet and exercise. Both test days will include the exercise component while the second test day will also include cognitive testing.
- These days had identical routines as the experimental test-days.
- Following the two baseline testing days, subjects were randomized. Randomization was equal: Each subject will have an equal chance of receiving either one of the three drinks at any one testing days. See the figure on Page 12 for an accurate simulation of this approach.
- At the Initial Test-Day Visit, subjects will receive either ABC's Energy™ or one of the two look-alike control drinks for a full day testing period.

- Subjects will complete self-reporting questionnaires at the Initial Visit, run-in test-days, and each of the six testing days.
- On each testing day, subjects will be asked to have breakfast upon waking.
    - They will visit the research clinic as soon after their breakfast as possible, where they will be measured and take their initial dose.
    - Those randomized for metabolic testing will have their initial metabolic test during the morning session.
    - Subjects will be reminded on the use of their pedometers.
    - They will then leave the Clinic and continue on their day until their noon Clinic appointment.
    - Around the noon hour, depending on whether it is an "A" or a "B" day, they will either (a) exercise according to their individualized plan (walking, jogging, tennis, equipment, etc.), and return to the Clinic afterwards for assessment, or (b) report to the Clinic for their VIGIL cognitive test.
    - Subjects must report to the Clinic in the late afternoon to report their experiences.
    - Subjects will be allowed to take an additional dose in the afternoon if they fell they need to in order to properly function. That is, if their afternoon energy level falls near or below their morning baseline period and they need the energy to work or perform in a normal manner.
- Subjects will report to the Clinic at approximately the same time for each visit. Since we need the subjects at the Clinic in the morning for the metabolic testing, all visits must be in the morning.
- Subjects must be available on the morning following each test day for a series of follow-up questions;
- The single site is an independent research facility where qualified research staff will see all subjects at each clinic visit (SOP; 2.2 The Research Staff).

Blinding Aspects and Procedures

- This trial is double-blinded;
- The identity of the specific treatment arm is not available to the clinical team, unless a medical emergency arises. The consulting physician is always able to gain access to this information.
- We use a multi-step process that assures this confidentiality. One of two study coordinators prepares the product bags that are given to each subject. Each bag is marked with a number that includes the study number and specific subject number. For example 12123 would be decoded as study number 121 and subject number 23.
- The study coordinators keep secured records as required by the IRB that includes the randomization scheme, subject identifiers, and other pertinent information. This information is kept from the nurses and biostatistician. In cases of medical problems the consulting physician or nurse typically acts without knowledge of the randomization. However, if the medical condition is considered serious the code may be broken. The IRB and the study sponsor will be notified under these circumstances as required by IRB guidelines.

Product Usage:

Taken once a day, in the morning;
Product delivered in cups;
Products were masked with small amounts of a placebo mix;

Placebo Mix:

Diet orange or diet Dr Pepper with tiny amounts of raw dried herbs

Inclusion Criteria

- Women and men who are interested in assessing commercially available energy drinks, have BMI's in the range of 20 to 37.5 m/kg^2, and are willing to exercise on the testing days;
- Women and men who are 18 to 60 years of age, inclusive, at the Initial Visit;
- Subjects in physical condition able to handle an increased energy period comfortably;
- Subjects who pass a compliance-screening test
- Subjects able to tolerate the active product and placebo
- Subjects who sign a consent form

Exclusion Criteria

Subjects who met any of the following exclusion criteria were not eligible for participation in this clinical trial:

- Were unwilling or unable to comply with any aspect of the clinical trial protocol;
- Were using any prescription or non-prescription products for energy or weight loss in the past 4 weeks; this list includes all fiber or laxative products;
- Are allergic to or express problems with any of the energy drink ingredients;
- Who had lost/gained more than 10 pounds of body weight in the last 3 months;
- Had severe co-morbid disease including cardiac, pulmonary, renal, hepatic, or active cancer; had any disease or condition that in the investigator's opinion compromises the integrity of the clinical trial or the safety of the subject;
- Consume alcohol at an elevated level; as defined as consumption of more than 14 standard alcoholic drinks per week; 12 ounces of beer = 4 ounces of wine = 1 ounce of hard liquor.
- Were insulin dependent diabetic;
- Had uncontrolled hypertension (defined as systolic blood pressure greater than 160 torr or diastolic blood pressure greater than 110 torr or by the study physician). Subjects taking antihypertensive medications were reviewed by the study physician prior to enrollment (randomization).
- Had had a surgery or a hospitalization within the past 3 months;
- Had an acute illness;
- Had a Body Mass Index (BMI) of less than 20 or greater than 40.0 m/kg^2;
- Had participated in a clinical trial in the past 4 weeks;
- Were taking methadone, insulin, anticoagulants, or similar medications;

- Women who were nursing, pregnant, or actively trying to become pregnant;

Severe co-morbid disease is defined as any condition that would cause severe limitations or inability to carry out usual activities of daily living.

The exclusion criteria identified above are based upon general safety concerns identified with the condition and/or product from recommendations made by the study physician, confounders identified by the biostatistician, or information identified in product ingredients' research.

Caution Criteria

Subjects who meet any of the following caution criteria will be strongly advised to consult with their primary care physician (PCP) prior to participating in this clinical trial:

- Those with a propensity to allergic reaction.
- Had a blood glucose (non-fasting, measured at the Initial Visit) of greater than 140 mg/dL;
- Had a fasting blood glucose of greater than 126 mg/dL evident with laboratory testing;

PRIMARY END-POINTS:

The primary efficacy endpoints are (1) research staff measurements and self-reports of:

- Energy, levels and strength
- Duration of elevated energy levels,
- Temporal sequence of energy levels throughout the day
- Timing of the 'crash'
- Level of the 'crash' compared to baseline
- Next day energy, fatigue, and alertness
- Exercise level
- Metabolic rates (subset)

The assessment of research staff measurements will be compared within subjects from measurements made during the run-in (at baseline) compared to the six test days.

Assess 'healthy energy' levels for the following time frames:

- Five, seven and nine-hour mark
- Total time of extended energy
- Peak energy levels
- Next morning energy levels

Assess the anticipated 'crash' following a period of extended energy:

- 'Crash' will be defined compared to each subjects' baseline level of energy and cognitive functioning, diagram a temporal relationship from beginning to the end of the day

Primary Endpoint: Energy

The difference between the end-of-the study weight and the baseline weight will be calculated for each subject. These differences will be tested statistically using unpaired t-tests (equal or unequal variances based on the actual variances) using the SPSS software (version 12, Chicago, IL.).

Differences of the means and the categories will be stratified by age, gender, baseline BMI, baseline weight, and the highest tertile of a co-morbid condition status. These potential confounders are historically the most important and thus require adjusting.

Regression models will be fitted using weight as a continuous variable and as a categorical outcome marker to determine if there are any additional confounders to report. These models will be helpful in explaining the results if any of the baseline characteristics are either clinically or statistically different.

Other End-Points:

- Taste
- Recommend product
- Quality-of-Life

ANALYTICAL METHODS:

Methods:

- Answers from survey tools were coded from 1 to 10
- Answers from the follow-up questionnaires were subtracted from each subjects' baseline data to create the outcome measures

Example:

Please write in the appropriate space, on the scale below, your rating for the symptoms:

0 1 2 3 4 5 6 7 8 9 10

For example, a subject answering the question about x at baseline and final give the following answers corresponding to the subsequent codes,

Time	***Answer***
Baseline	*8*
Final at 3-months	*2*

The subtraction of the codes renders a point improvement for this subject on this question:

8 – 2 = 6 point improvement

- The answers for the two groups (placebo and treatment) for each symptom were summed. This forms the basis of the results.
- Differences in the means between the treatment and placebo groups were analyzed using the paired or unpaired t-test, where statistical significance was pre-determined to be < 0.05.

Categorical Analysis:

- One-to-two point differences have been classified as "some improvement", while three-to-four point differences as "significant", and five or more point improvements as "dramatic".
    - No Improvement
    - Any Improvement: One point or greater
    - Some Improvement: Specifically one-to-two point improvement
    - Significant Improvement: Specifically three-to-four point improvement
    - Dramatic Improvement: Specifically five-or-more point improvement
- All categories were analyzed using the Chi-Square test. Some analyses used Fisher's Exact Two-Tail t-test, due to the small cell limitations. Fisher's is another type of chi-square test that must be utilized during scenarios of small cell sizes.
- These category improvements were determined a priori by the medical advisory group

TRIAL RESULTS

A total of 63 subjects consented, but only 58 began the trial. Forty-two individuals completed all the testing aspects. The drops were self-imposed.

Baseline Characteristics

The following data defines the study population.

Parameter	Percentages
Males	63%
Females	37
Black	11.1%
Hispanic	7.4
White	81.5

Clerical	4%
Craftsperson / technical	11
Management	4
Professional	11
Service Industry	22
Student	15
Not Working	22
Number of Hours Working	**Percent**
Full-Time	42%
Part-Time	26
N/A for Hours working	22

Vital Statistics

Parameter	Mean	Std. Dev.
Age	27.4	11.1
Height	68.4	4.5
Weight	165.2	41.4
BMI	26.8	5.5

Age Distribution

Age Categories	Percentage	Cumulative Percent
18 – 19	16.3%	16.3
20 – 24	32.7	49.0
25 – 29	16.3	65.3
30 – 34	6.0	71.3
35 – 39	4.0	75.3
40 – 44	6.3	81.6
45 – 49	6.0	87.6
50 – 54	10.1	97.7
55 -59	2.0	99.7

The mean age was 27.4 years with a range from 18 to 57. Even though nearly half were 24 or younger, there was a steady number of subjects from 30 onward demonstrating that this represented a wider range than just teenagers and those in their early twenties.

Alcohol Consumption

Parameter	Percentages
None	56%
<1	7

1-2	7
3-4	4
5-6	7
7-8	4
9-10	4
11-14	4

Mean Alcohol Consumption per Week

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Level of Alcohol per Week	1.5	2.0	0.9	2.1

The amount of alcohol consumed is remarkably low for this population. Even though this is a self-report statistic, the research staff had no reason not to believe it.

Self-Report Weekly Exercise Levels

Parameter	Percentages
<1	4%
1-2	11
3-4	15
5-6	26
7-8	15
9 or more	11

Self-Report Health Status

Parameter	Percentages
Excellent	26%
Very Good	44
Good	15
Poor	4
Fair	0

Medical History

Parameter	Percentages
Diabetes	4%

Hypertension	4
Thyroid	4
Asthma or COPD	0
Heart Disease	0
Depression	15
Serious Injury	22
Surgery	56
Kidney	0
Gallbladder	0
Liver	4
Gastrointestinal	11
Ulcer	7
Cholesterol	4
Cancer	0
Osteoarthritis	0
Rheumatoid arthritis	4
Neurological problems	0
Blood Disorders: anemia, etc.	0
Gout	0
Migraines	4
Skin Conditions	0
Diet Restrictions	1
Other	7
On Meds	30
Smoking	45
Supplements	26
Allergies	11

Despite a wide age range, this population represents a fairly healthy population with the exception of smoking and possibly depression. Smoking is high in this group but may represent the type of individual that wishes to assess energy drinks. While depression may seem high, it is not compared to the general population. Other notable low risk levels include diabetes (4%), asthma (0%), cardiac or hypertension (4%), and arthritis (4%).

Surgery Types

Type of Surgery	**Numbers**
Hip	N= 3
Tubal ligation	3
Oral surgery	3
Tonsil	2
Various	1

'Various' includes back, tonsils, hysterectomy, hernia, gallbladder, appendix, thumb, and knee

Caffeine Intake

Caffeine Per Day (cups)	Percentages
0	19%
1	23
1.5	4
2	19
3.5	4
4	12
5	12
6	4
8	4

Mean Daily Caffeine Consumption

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Daily Caffeine	2.0	1.9	1.4	2.5

The average amount of daily caffeine was 2 cups or equivalent with a surprisingly narrow confidence interval, despite the distribution that ranged from none up to 8.

Caffeine Types

	Percentages
Coffee	48%
Caffeinated Soda	33
Coffee and Caffeinated Soda	19
Caffeinated Teas	5

Coffee drinkers, as solo or combined, represented two-thirds of this population while soda drinkers as solo or combined represented half the group.

Energy Drinks (on average)

	Percentages
Never	61%

Occasionally	8
1 Every Other Day	8
1/Day	15
Approx 3/day	8

Mean Daily Energy Drinks

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Daily Caffeine	0.41	0.9	0.14	0.68

The average amount of energy drinks was less than half per day, with a corresponding 95% confidence interval between 0.14 and 0.68 drinks per day. This is remarkably LOW for a group testing these drinks and dramatically reduces potential biases in this study.

Baseline Average Energy (over the past week)

Subjects were asked to rate their average and peak levels of energy over the previous week. A rating of '0' meant the individual had almost no energy while a '5' meant they were experiencing an average amount of energy, and a '9 would be their ideal setting with everything going extremely well, just short of 'bouncing off the wall'.

We notice that this specific population exhibited a bimodal distribution, with the first peak centered on '4-5' on this scale, while a second group peaked at '7'. This indicates a normal response to this question that we have seen in other trials. It is important to remember that this is a self-report question and provides a valuable insight in how they view their average energy level and that no one can validate their responses.

Average Energy Levels Over the Past Week

10-Point Scale: 0= No Energy; 9 = Highest	Percentages
0	0%
1	0
2	0
3	4
4	16
5	32
6	8
7	32
8	8

9	0

Peak Energy (over the past week)

Like the questions concerning their 'average' energy, this related questions asked about their peak energy level (using the same scale).

For the most part, all subjects, except one, rated their peak above their average. The raw data shows that those reporting an average of '7 and 8' moved their peak to '9', while those reporting an average from '4' to '6' reported their peak between '6 to 8'.

10-Point Scale: 0= No Energy; 9 = Highest	Percentages
0	0%
1	0
2	0
3	0
4	4
5	0
6	4
7	32
8	20
9	40

Mean Energy Levels at Baseline

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Level of Energy	5.2	1.4	4.8	5.7
Peak Level of Energy	7.6	1.5	7.1	8.0

The 95% Confidence Intervals demonstrate how close the entire group was in terms of their baseline energy levels. Statistically, there were very few outside of a narrow range with respect to their baseline energy levels. This is a good finding for comparing their future experiences in assessing the various drinks.

Comprehensive Metabolic Profile Results

Laboratory Parameter	Mean	Std. Dev.
Electrolytes		
Calcium	9.63	0.26
Chloride	103.9	2.0
Potassium	4.29	0.27
Sodium	140.3	1.6
Renal Function		
BUN	12.9	3.1
Serum Creatinine (Scr)	0.93	0.15
BUN: Scr Ratio	14.2	4.2
Albumin	4.55	0.24
Proteins (total)	7.34	0.4
Globulin	2.79	0.4
Albumin Ratio	1.66	0.2
Liver Function and Related		
Bilirubin	0.61	0.3
Glucose (non-fasting)	100.9	20.8
Alkaline Phosphatase	86.9	20.1
AST	19.5	5.2
ALT	20.4	9.1

We note that no individuals in this trial had abnormal baseline comprehensive metabolic laboratory (CMP) values. All these numbers are in the normal range.

STUDY END-POINTS:

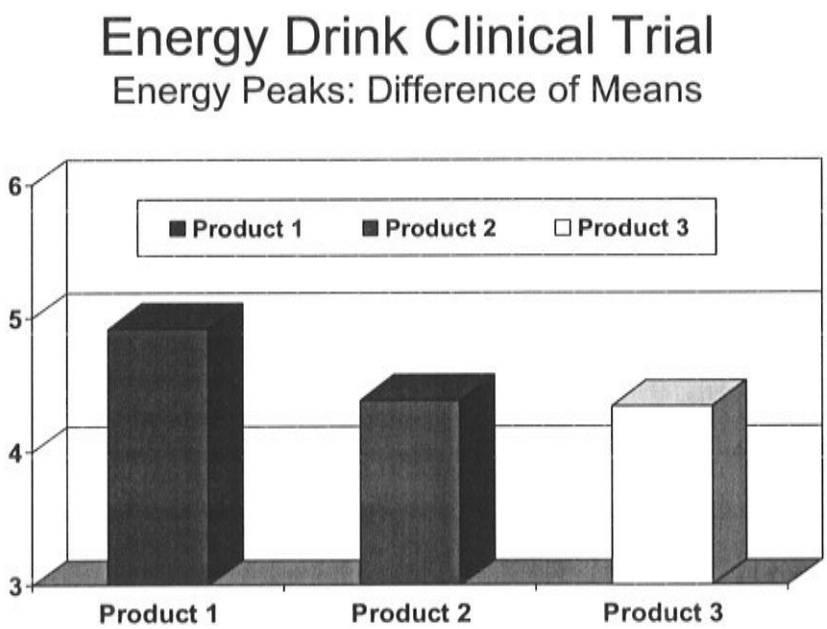
Peak Duration End-Point:

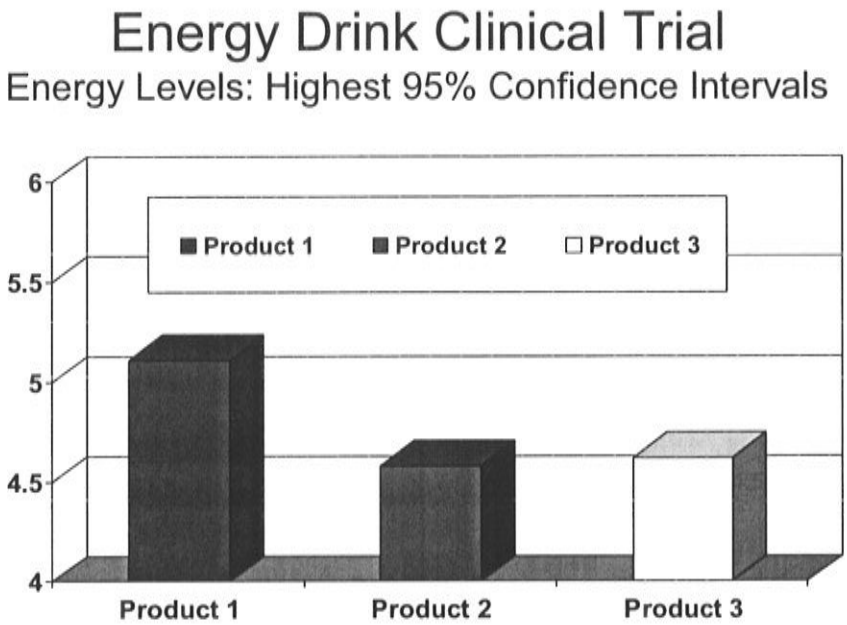
This end-point is the mean and 95% Confidence Interval (C.I.) for the number of hours that each drink showed a noted increase.

For example, Product 1 had the longest period of increased activity of 4.92 hours. Ninety-five percent of the time, one would expect that range to include the interval (C.I.) from 4.7 hours all the way up to 5.1 hours. Both Product 2 and Product 3 had similar results for their means and C.I. between these two products, but were both lower than Product 1 Energy.

Mean and Range of Energy Peaks in Hours following Ingestion

	Mean	Std. Dev.	95% Confidence Interval Lower Limit	95% C.I. Upper Limit
Product 1	4.92	0.71	4.74	5.11
Product 2	4.39	0.52	4.21	4.58
Product 3	4.34	0.68	4.11	4.59



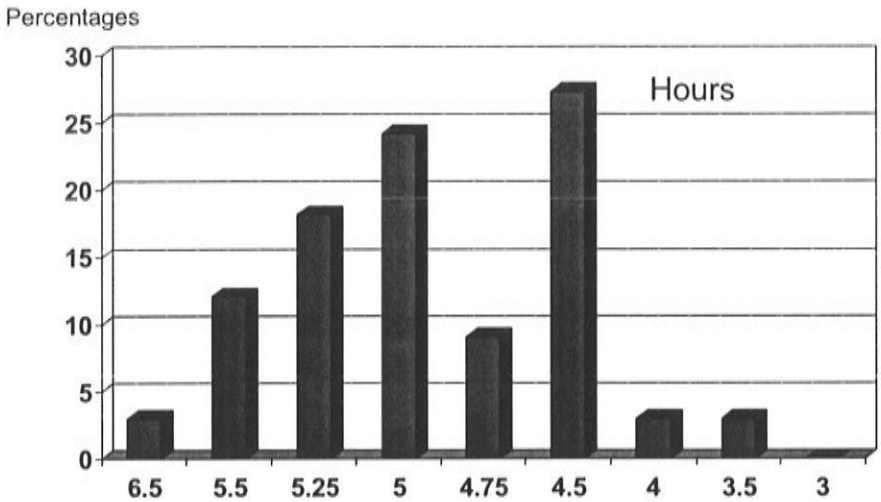


Product 1

Peak Hours	Percent	Cumulative Percent
6.5	3.0	3.0
5.5	12.1	15.1
5.25	18.2	33.3
5.0	24.2	57.5
4.75	9.1	66.6
4.5	27.3	94.0
4.0	3.0	97.0
3.75	3.0	100
3.50	0	100
3.25	0	100
3.0	0	100

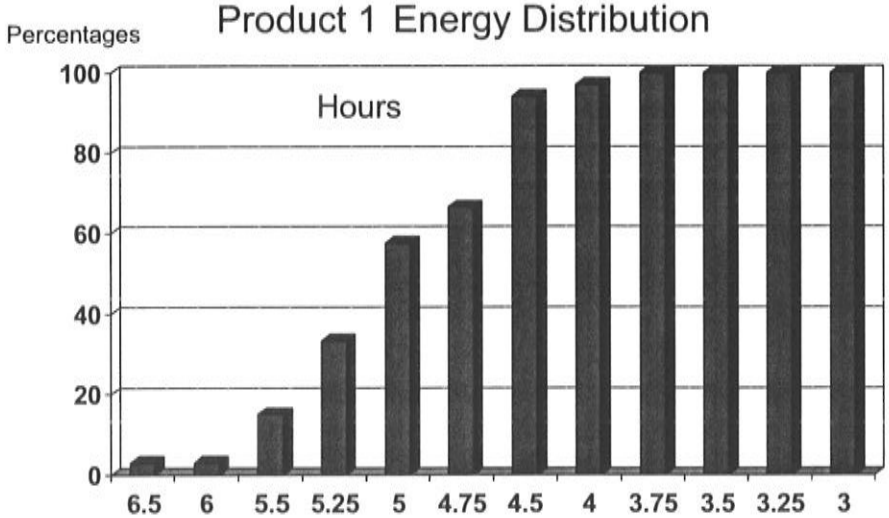
Energy Drink Clinical Trial

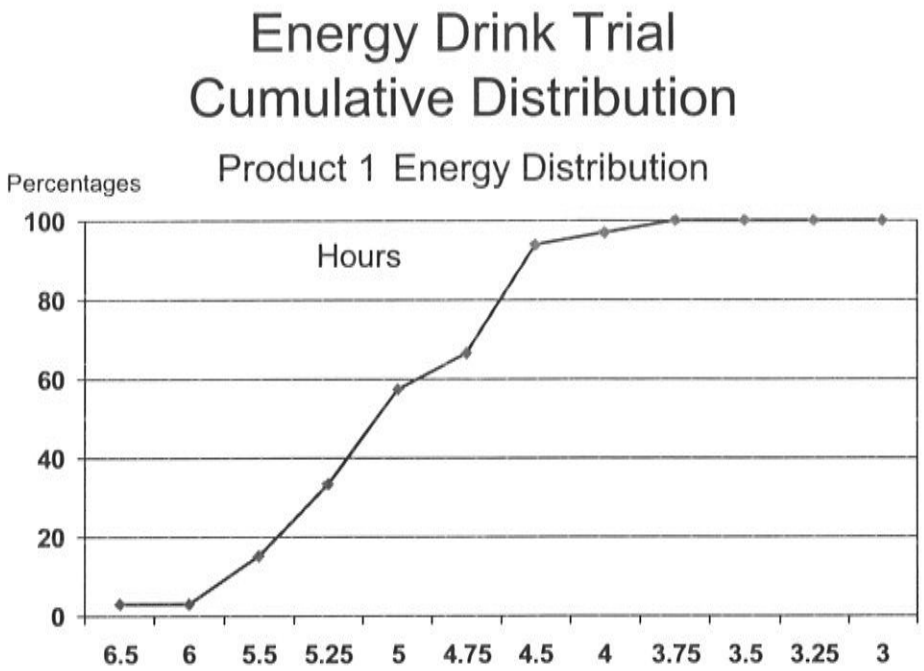
Product 1 Energy Distribution



Energy Drink Clinical Trial
Cumulative Distribution

Product 1 Energy Distribution



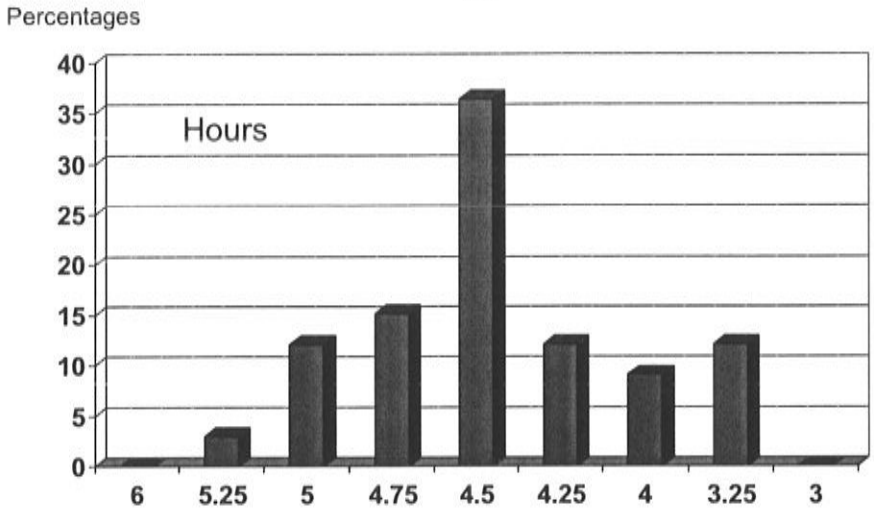


Product 2

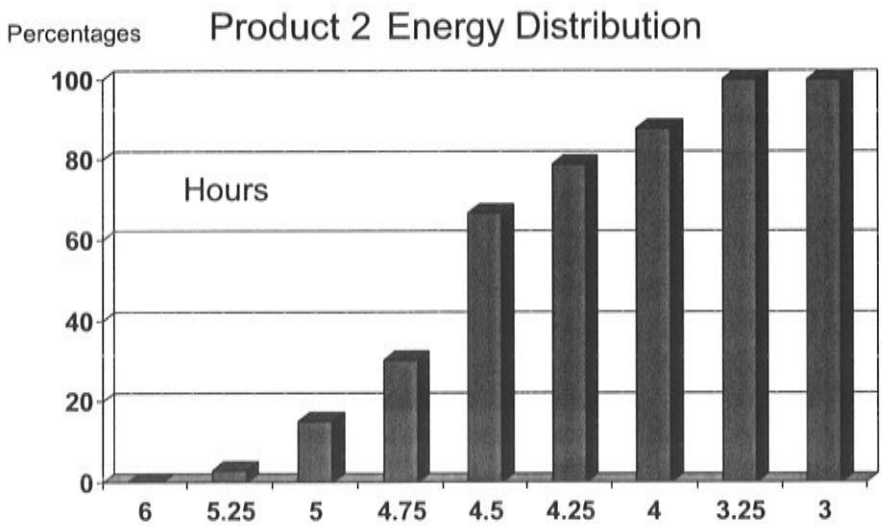
Peak Hours	Percent	Cumulative Percent
6.0	0	0
5.25	3.0	3.0
5.0	12.1	15.1
4.75	15.2	30.3
4.5	36.4	66.7
4.25	12.1	78.8
4.0	9.1	87.9
3.25	12.1	100
3.0	0	100

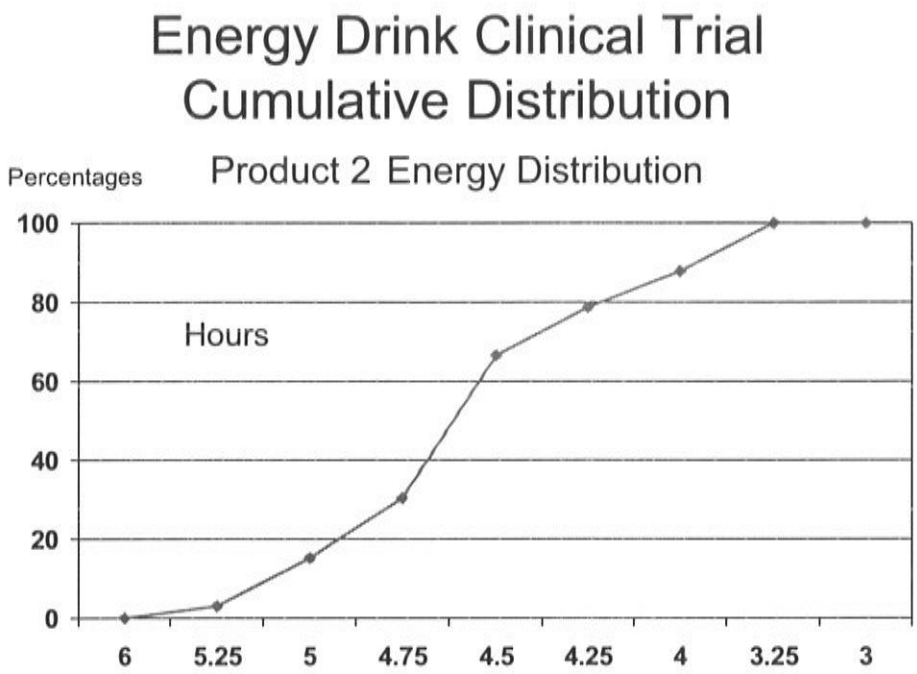
Energy Drink Clinical Trial

Product 2 Energy Distribution



Energy Drink Clinical Trial
Cumulative Distribution



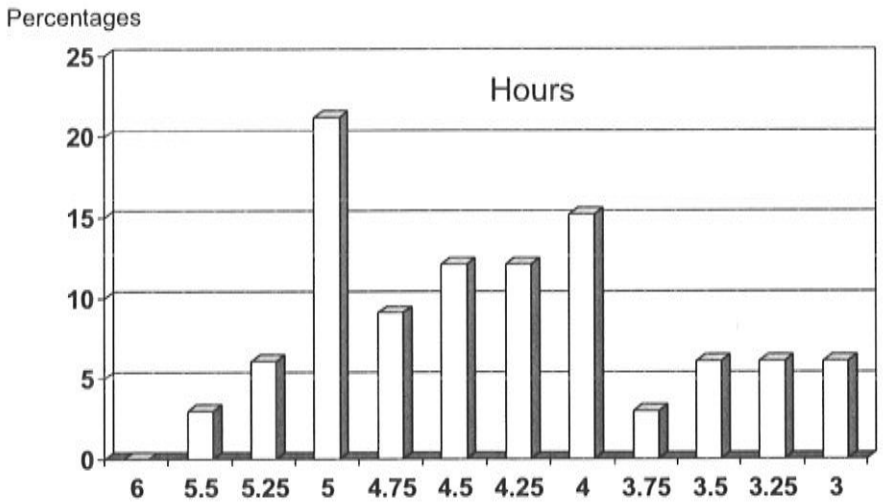


Product 3

Peak Hours	Percent	Cumulative Percent
6	0	0
5.5	3.0	3.0
5.25	6.1	9.1
5.0	21.2	30.3
4.75	9.1	39.4
4.5	12.1	51.5
4.25	12.1	63.6
4.0	15.2	78.8
3.75	3.0	81.8
3.5	6.1	87.9
3.25	6.1	94.0
3.0	6.1	100

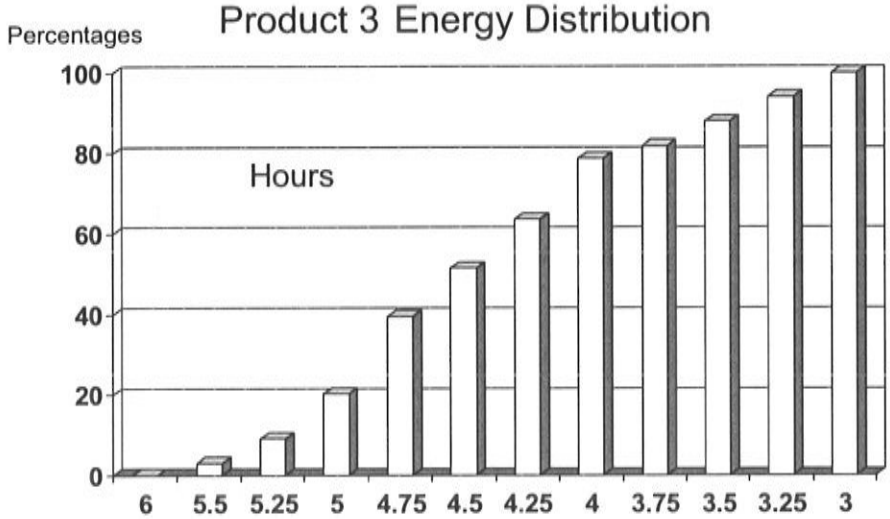
Energy Drink Clinical Trial

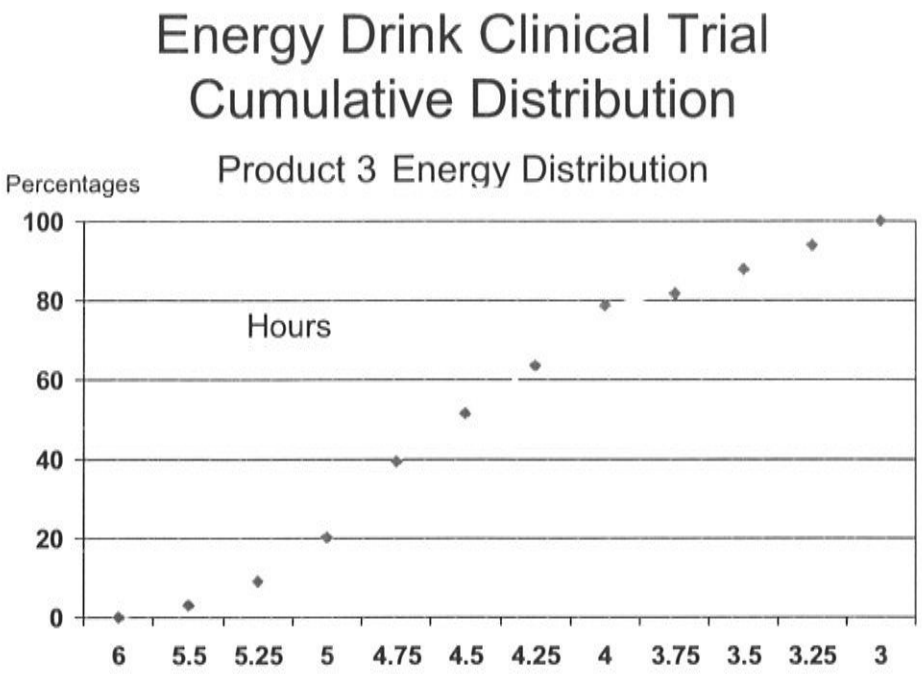
Product 3 Energy Distribution



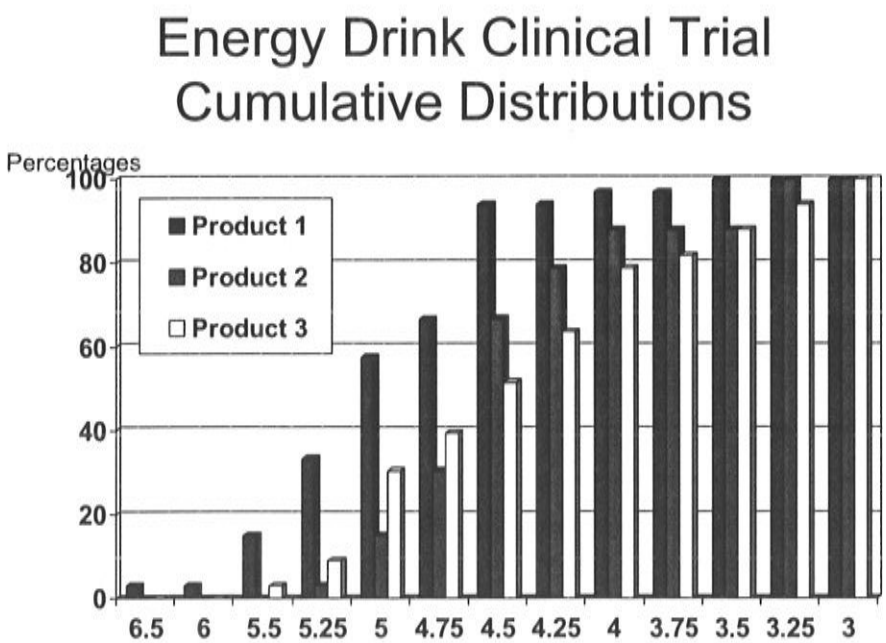
Energy Drink Clinical Trial
Cumulative Distribution

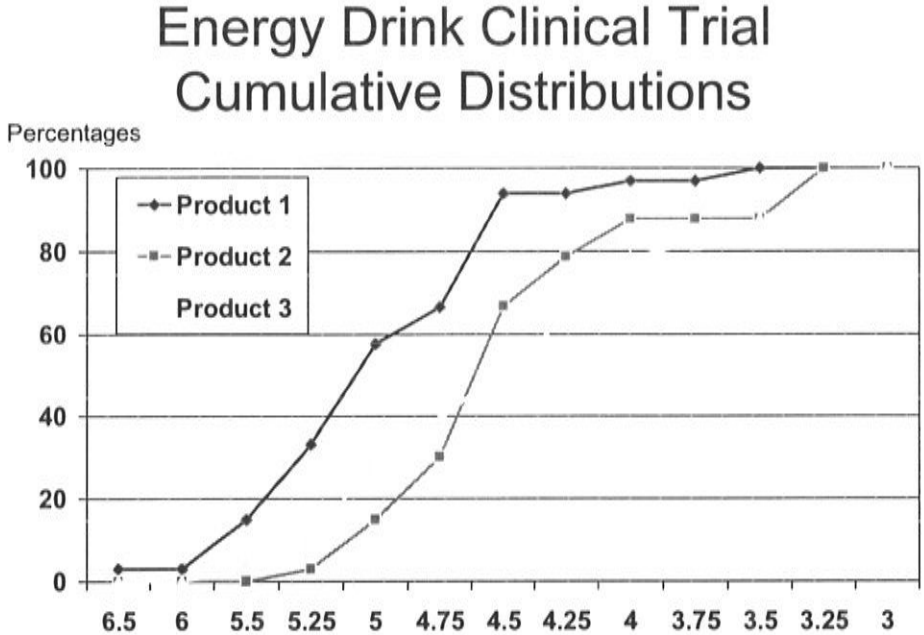
Product 3 Energy Distribution





Comparing the Cumulative Distributions:





In this 3-way line graph comparison, it is easier to observe that the Product 1 curve is shifted to the left, whereas the Product 2 and Product 3 are intertwined and are essentially the same performance. The interpretation that the Product 1 curve was shifted to the left means that more individuals taking Product 1 reported longer intervals of energy, than when they took the other products.

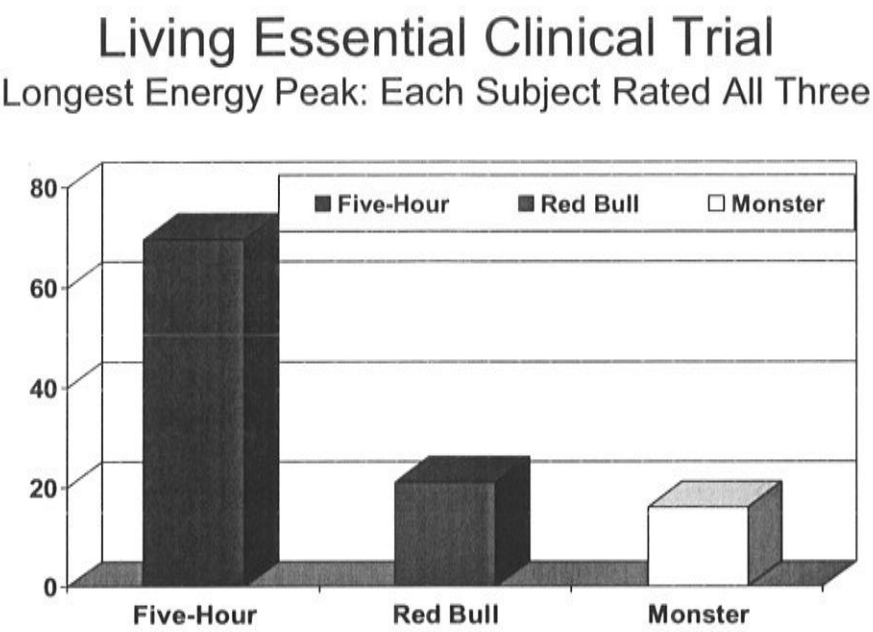
This graph shows that close to sixty percent of test subjects experienced five or more hours of energy from Product 1 versus thirty percent for Product 3 and twenty for Product 2. The study showed that ninety-four percent of test subjects had 4.5 or more hours of energy from Product 1 versus fifty-two percent for Product 3 and sixty-seven for Product 2.

Number of times for each beverage, a given individual named the specific drink the <u>longest peak hours</u>

5 – Hour	Product 2	Product 3
69.7%	21.2%	15.2%

Includes two ties between Product 1 and Product 3.

For this question, regardless of taste factors, individuals preferred Product 1 for the energy component approximately 3 to 1 over the other drinks.



Crash Data

Mean and Range of Crash, as Defined as Following Peak (Hours)

This interval (time in hours) is measured from the peak (highest energy) until the point in time when the individual felt they had reached the low point of the day (the 'crash'). The shorter the time in this graph indicated that the person crashed in a shorter time period, while those with longer times had a more gradual slowing of their energy.

	Mean (hrs)	Std. Dev.	95% C.I Lower Limit	95% C.I. Upper Limit
Product 1	2.43	0.5	2.2	2.6
Product 2	1.36	0.4	1.2	1.5
Product 3	1.43	0.3	1.3	1.5

Notes on the Crash:

Nearly eighty percent (32/41) and three-quarters (29/40) of those taking Product 2 and Product 3 respectively, reported a Moderately-SEVERE crash that left them extremely tired and in need of rest, another drink, or some other action. Only twenty-four percent (10/42) of those taking Product 1 had similar reactions.

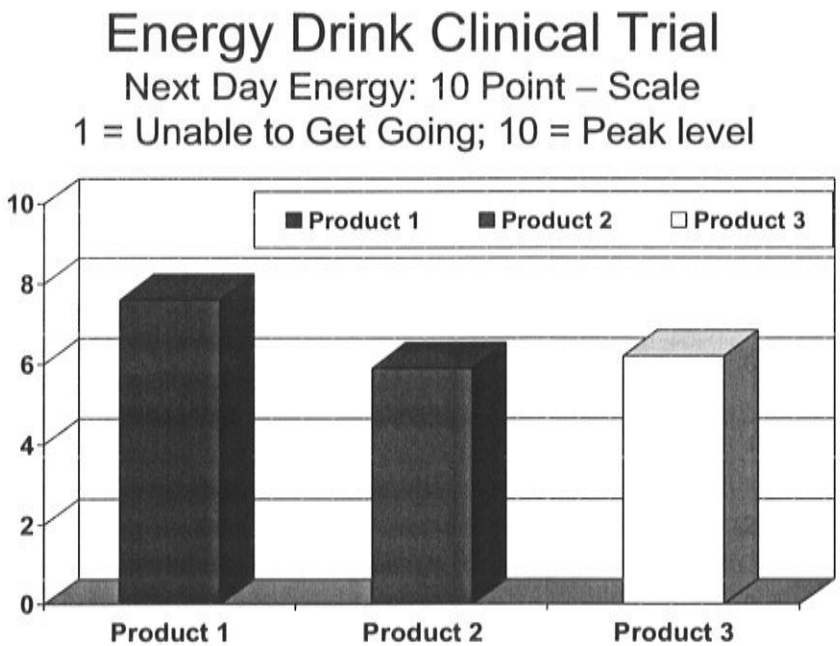
Next Day

How Do You Feel Today? (Asked by the research staff the following morning)

1 = Unable to get out of bed or get going

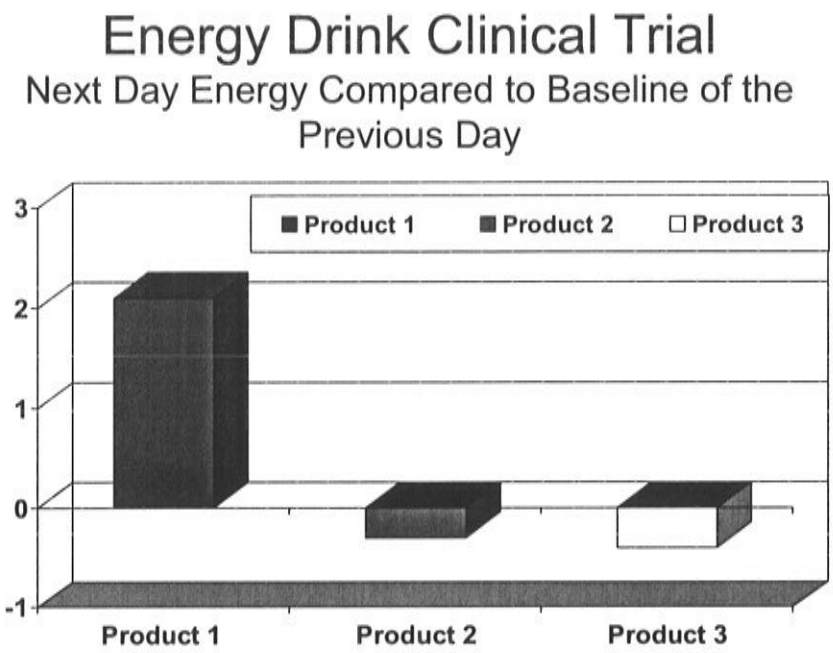
5 = Normal Level of Activity

10 = Peak Energy Level



Next Day Energy

5 – Hour	Product 2	Product 3
7.6	5.9	6.2



Next Day Energy Compared to Baseline of the Previous Day

Product 1	Product 2	Product 3
2.1	- 0.3	- 0.4

A positive number indicates that individuals rated their energy HIGHER the following day as compared to the day of testing. A negative number signifies that the test subjects reported less energy the following day compared to the test day.

Thus, both subjects when testing Product 2 and Product 3, reported slightly less energy the following morning compared to the test day. Product 1 had higher energy the following day.

CONCLUSIONS:

In this randomized, product-controlled, double-blinded, cross-over clinical trial, three different 'energy' beverages were assessed using identical procedures. Subjects were screened based on Institutional-Review Board approved entrance criteria and underwent a placebo testing prior to testing each of the different energy beverages. The testing schedule was randomized meaning that each subject took the different beverages in random sequences.

All testing was done on a day-long basis requiring that each subject appear in the morning and afternoon. Subjects needed to be fully rested and had to allow a minimum of one day between testing days. Energy drinks were not permitted throughout the testing and

alcoholic consumption was also prohibited. Every effort feasible was made to have unbiased testing of each different drink.

The baseline data for the cohort showed the following characteristics: sixty-three percent were males, which is not surprising but over a third of the group were women ensuring a mix of the genders. The average age was 27.4 with a standard deviation of 11 meaning that we had a full age range in this study and did not have an overabundance of twenty year old males. Eighteen percent of the group was of minority race also contributing to a healthy mix. The Body Mass Index was 26.8 +/- 5.5 indicating only a slightly overweight population. The group, on average, consumed two cups of caffeine drinks per day. This amount fits well within bounds of normal Americans and did not represent a group relying on high caffeine and large amounts of energy drinks. Actually sixty-one percent of the group had never had an energy beverage prior to the study and many indicated that this test offered a safe environment to assess them. Only eight percent normally consumed more than one energy drink a day on average.

The baseline lab data which included a complete metabolic profile, blood pressures, and pulse also were well within normal ranges. This provided assurance that none of the subjects had obvious metabolic disorders, and thus, was approved for testing.

An important conclusion is that this test population had few outliers with respect to their baseline data and most, if not all, of their behavioral tendencies fell within normal ranges.

Testing:

The data presented in this study was complete in that each subject tested all three beverages according to protocol.

With regards to the time frame associated with peak performance, Product 1 was the highest with a score of 4.92 hours, followed by Product 2 at 4.4 and Product 3 at 4.3 hours.

Nearly seventy percent of all subjects chose Product 1 as the best performer when it came to which beverage had the highest and longest effect. These two data points strongly indicate that Product 1 outperformed the other two beverages.

The crash or let-down data also supported Product 1 in that the subjects testing Product 1 had a more gentler let-down and did not go below their baseline, whereas the other drinks exhibited a crash that brought the energy of the subjects BELOW their morning energy level.

The actual peak levels achieved by each drink were comparable and no statistical differences were found.

There were several categories that did not show any differences between the drinks. These included the cognitive testing, metabolic rates, and exercise parameters.

In summary, for the primary end-points, Product 1 outperformed the other two beverages.